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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/937,756	09/25/1997	DAVID C. RUEGER	CIBT-PO6-504	2132

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BOSTON, MA 02110-2624

EXAMINER
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TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/30/2003

64

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/937,756

Applicant(s)

RUEGER ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 97,99 and 105-108 is/are pending in the application.
- 4a) Of the above claim(s) 97, 99 and 105-108 in part is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 97, 99, 105-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 97,99 and 105-108 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Claism 97, 99 and 105-108 to the extent of SEQ ID NO's 29 and 31 are withdrawn.

### **DETAILED ACTION**

1. This action is supplemental to the action mailed 9-24-03, Paper No. 45 and sets forth the proper period for response.
2. The amendments filed 2-5-03, 4-25-03, and 7-23-03 have been entered into the record and have been fully considered. Claim 91 is canceled. Claims 97, 99 and 105-108 are pending.

### ***Election/Restrictions***

3. Applicant's election with traverse of Group II, to the extent of a polypeptide having the amino acid sequence of human OP-1 (SEQ ID NO:5) in Paper No. 44 is acknowledged. The traversal is on the ground(s) that the different morphogens are linked via structure and that there is no burden.

This is not found persuasive. Applicant's shift of invention to Group II upon the filing of an RCE has been granted. All claims are directed to the Group II invention. However, as set forth in the restriction requirement of 11-29-02, Paper No. 40, the different morphogens are identified by distinct sequence elements that lack common structure. Thus the distinct peptides constitute different inventions requiring different search and examination as a reference to any one particular element would not be shared with any other. Applicant's indication in Paper No. 44 to elect the polypeptide element of a polypeptide having the amino acid sequence of the C-terminal seven-cysteine skeleton on human OP-1 (SEQ ID NO:5, residues 38-139) with traverse is noted. It is also noted that the particular morphogens sharing this structure are subject to rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

4. Amended claims 97, 99 and 105-108 are newly drawn to elements (4) and (5) directed to SEQ ID NO's 31 and 29. These inventions are directed to inventions that are independent or distinct from the inventions originally claimed because the sequences are distinct as they are characterized by distinct amino acid compositions that do not share common structure with the elected sequence of SEQ ID NO:5, residues 38-139. This is evidenced by the fact that the pending search file fails to match SEQ ID NO:5 residues 38-139 with SEQ ID NO's 29 and 31. Accordingly, the searches are not co-extensive and a reference against any one element would not necessarily be a reference to any other. The search of the elected sequence does not encompass a search for newly presented SEQ ID NO's:29 and 31.

Therefore, since applicant has received an action on the merits for the originally presented invention (SEQ ID NO:5, residues 38-139), this invention has been constructively elected by original presentation for prosecution on the merits.

5. Accordingly, claims 97, 99 and 105-108 in part, to the extent of claims 97 and 99 elements (4) and (5) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The Examiner has considered applicant's arguments presented in Paper No. 44, filed 7-23-03 but these arguments are not persuasive as the sequences lack common core structure.

#### ***Claim Objections***

6. Claims 97, 99 and 105-108 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in *In re Weber* \*\*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

In particular the withdrawn subject matter of SEQ ID NO's:29 and 31 are non-elected and lack common core structure with the sequence of SEQ ID NO:5, residues 38-139 already examined.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 97, 99 and 105-108 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant's claims 97 and 99 are newly amended to recite % identity to a subsequence of SEQ ID NO:5. The following notations as recited in claim 97 and 99

appear to lack written description support in the specification as originally filed. Point (1) newly recites "a conserved C-terminal seven-cysteine skeleton 60% identical to residues 38-139 of SEQ ID NO:5" and Point (2) newly recites "a conserved C-terminal seven-cysteine skeleton 70% homologous to residues 38-139 of SEQ ID NO:5".

Support is found for the recitations as specified in the specification at p. 53, lines 27-32 and p. 46, lines 28-30, including 60% or 65% identical sequences with a conserved six cysteine skeleton of residues 43-139 of SEQ ID NO:1. However, no support is found for the recitations as recited in the claims as noted above. Thus, the amended recitations constitute new matter absent evidence of support in the specification as originally filed.

#### **Status of Claims**

9. No claims are allowed.

#### **Conclusion**

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.



Sharon L. Turner, Ph.D.

Application/Control Number: 08/937,756

Page 6

Art Unit: 1647

September 29, 2003